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LLNL chooses OHRP-provided QA consultation -

Lawrence Livermore National Laboratory chose OHRP QA consultation rather than accreditation because the nature of the lab's research made it a better choice

Ann-Marie Dake

When Ann-Marie Bucaria Dake volunteered Lawrence Livermore National Laboratory (LLNL) for an Office of Human Research Protections (OHRP) QA consultation, she wasn't worried.

Well, mostly she wasn't worried.

She knew the program was sound, the people extraordinarily capable, and the IRB seriously conscientious about its responsibility to oversee human subject research.

Still, a visitor from Health and Human Services' Office for Human Research Protections (OHRP) would carefully examine documents, scrutinize procedures, and talk to everyone during the assessment process. In addition, the two DOE human subjects program managers would also be part of the team.

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Something could go wrong. Some documentation may be missing. Some procedure possibly unacceptable or vague.

Paying off

But none of that happened. The assessment is complete; the results were even better than she hoped, and the care that she and others took to assure the assessment went well is paying off because LLNL's program is now even better organized than it was before.

LLNL was the third national laboratory to participate in an OHRP QA consultation. Both Oak Ridge and Sandia National Laboratories completed the process in 2008. Brookhaven National Laboratory chose to seek accreditation from the Association for the Accreditation of Human Research Protection Programs, which it achieved in September 2010.

Dake acknowledged that the preparation and the subsequent on-site visit by OHRP and DOE was stressful just because that is the natural response when another set of eyes, or sets of eyes in this case, is reviewing your work.

"But I came to understand that there was no need to be worried, in part because they are not coming 'for cause,' or because there was 'something wrong,'" she said. "They're coming to review and help, not to impede, punish, or criticize. It's an educational visit."

On-site review team

The on-site review team consisted of Elizabeth White, DOE Human Subjects Program Manager; John Ordaz, the NNSA Human Subjects Program Manager; and Michelle Feige, a public health analyst with OHRP.

Dake said LLNL chose self-assessment rather than accreditation because of the nature of research at the Lab. The DOE management supported this choice.

"Many of the Lab's studies are collaborations with University of California campuses and are biomedical in nature. We also deal with on-site studies involving potentially vulnerable populations such as other lab workers who could feel coerced into participating in the research study. However, at this time the Lab is not involved in clinical trials or FDA-regulated research, which is why we felt that OHRP's process of self-assessment would be more useful and applicable to us," she said.

Advice for others

Her advice for others who choose QA consultation is to thoroughly examine and organize all documentation, perform an extensive file review, and send as much information as possible to OHRP and/or DOE in advance of their on-site visit (that is, if your organization agrees with this method.) Both OHRP and DOE had requested a number of documents in advance of their visit. Dake and John Knezovich, the IRB Chair, felt it was in everyone's best interest to comply with the requests.

"When they get here, time is short. We thought that if some of the work could be reviewed prior to the visit, they would have more time to discuss issues and suggestions when they're here. This was indeed the case, and afforded all parties the opportunity to have a cogent, focused conversation regarding various aspects of our program."

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She also suggests talking to people at other labs about their experience. "I spoke with my colleagues at the National Laboratories who had completed the process. This proved to be very helpful in describing what to expect. Hearing it firsthand from someone who had completed the process was both reassuring and enlightening."

Among the work she did to prepare was a complete revamping of the program's Web site. Dake wrote an entire set of standard operating procedures (SOPs) while revising the IRB Policies and Procedures.

In addition, she worked with an IT individual to have all the IRB forms redone into a PDF format, which is the format of choice at LLNL. "We now have a new set of standard operating procedures for our IRB. The new PDF forms are user friendly, current, and have an overall 'cleaner look,'" she said.

They do find things to pull out, as all reviewers do, but they were always things that will strengthen our program.

Discussions with board members

Dake and Knezovich also discussed at length the planned assessment with the IRB members, ensuring, among other things, that they were fully knowledgeable about the new SOPs and the agenda for the visit.

Prior to the visit, Dake and Knezovich organized a telephone conference with the review team and LLNL's Institutional Official, Thomas Gioconda, who could not be present for the inbriefing (due to previous commitments). Dake and Knezovich felt this step was essential as Gioconda was new to the Laboratory and the IRB. This was well received by all parties involved and afforded an informal way to dialogue and discuss the details of the impending visit.

During the on-site visit, the review group spoke with board members "and that went especially well," she said, "because every one of our Board members came to the meeting, which I thought said a lot about their interest in participating and strong dedication to our program."

The review group also spoke with six principal investigators who discussed their experience interacting with the IRB. "While that was going on I met with Michelle Feige to go over in great detail all of our policies and procedures, SOPS, protocol files, and other documentation."

The visit, which lasted a day and a half, included an inbriefing during which the review team discussed what they would do, as well as an outbriefing, when they talked about what they found, highlighted the noteworthy practices, and offered suggestions for improvement.

The comments from the review group were both helpful and positive, Dake said.

Tweaking

"It went exceptionally well, largely because we had all the elements together. Some of what we do needed a little tweaking, which we are doing now; however, because we had a good program to begin with this was mostly a matter of getting everything together, getting it as close to perfect as possible in our eyes. Then, when our visitors came we could say, 'This is who we are.'"

Dake said that it is important to understand that the process is thorough but that the review group is there to help. "They do find things to pull out, as all reviewers do, but the comments were sound, which will ultimately strengthen our program.

"This is an evolving process," she said, "as new and revised guidance will continue to be generated within the human subjects' community, and change is an ever-present element. However, we know our program has a strong foundation on which to grow."Δ